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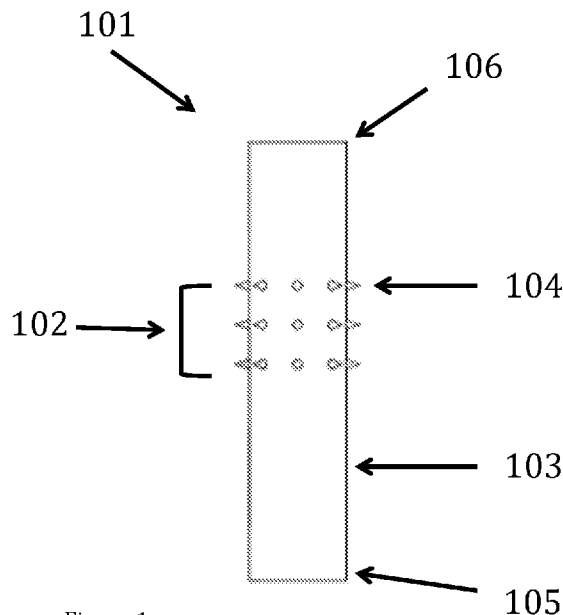


Figure 1

(57) Abstract: The invention relates to a catheter used as medical equipment and with serrations on it, and to the use of these catheters during the withdrawal or administration of fluids, blood and blood products to patients or during processing within the body cavity.



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NOVEL CATHETERS WITH INFECTION RESISTANCE AND WIDE RANGE OF USE

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TECHNICAL AREA

The invention relates to a catheter used as medical equipment and with serrations on it, and to the use of these catheters during the withdrawal or administration of fluids, blood and blood products to patients or during processing within the body cavity.

PRIOR ART

A catheter is required to provide a way in patients who need large or small, arterial or venous intravenous access. Administering or receiving fluid, blood and blood products to the patient or in cases where an intravenous nutritional supplement is required or when a vascular access or an operation into the body cavity is required materials such as catheter, cannula, etc. can be used to perform these procedures.

By placing the catheter in the appropriate vein (central vein, arteries, etc.) or in the body cavity, the desired procedure may be performed. Catheters are available on the market for different purposes for use in patients in different procedures.

When existing catheters are examined, it is determined that infection occurs in patients who use catheters due to the physical structure of catheters. The first of these reasons is that the size of the catheter is longer than needed. As a result of the studies and clinical experience, it was concluded that when the catheter length is longer than necessary, the tendency to infection in patients is increasing. Another cause of infection in catheterized patients is the microorganisms entering the body from the base of the catheter, that is, from the skin tissue in which the catheter is in contact. This type of infection occurs in 2 ways; (i) bacterial penetration between the catheter and the skin, as there is insufficient granulation tissue between the catheter and the skin, or (ii) Increasing bacterial colonization on the catheter by movement of the catheter back and forth from where the catheter enters the skin, which results in taking the bacterium from the skin surface into the blood, or by moving the

catheter in and out of the skin surface. Thus, bacteria or microorganisms are transported from the skin (externally) to subcutaneous tissue and/or into the blood.

In the prior art, permanent catheters made of felt have been developed to overcome this problem. However, the felt has a risk of infection as it creates an area where there is a lot of dead tissue under the skin that can prevent the immune cells produced by the body against bacteria reaching the infection area because of the requirement of overcoming the formed dead tissue to reach the infected area.

Considering the state of the art and from the clinical experience of specialist physicians working in this field, it is seen that new types of infection resistant catheters should be developed

BRIEF DESCRIPTION OF THE INVENTION

The present invention relates to all types of medical catheters comprising a serrated area (Figure 1, Figure 4, Figure 8) to eliminate the aforementioned disadvantages and bring new advantages to the related technical field.

The term "medical catheter" as used in the context of the invention refers to a group comprising; aspiration catheters, urinary catheters, angioplasty balloon catheters, arterioscopes, cannula for neurological or cardiac use, cardiovascular catheters (e.g. angiography, atherectomy, angioplasty, pericardium excretion, septostomy or vulvoplasty catheters), neurological catheters, dialysis catheters, urological catheters, peripheral venous catheters, central venous catheters, peripherally placed central catheters.

It is an object of the invention to provide catheters with reduced risk of infection.

The present invention relates to catheters (101, 201, 301) comprising a serrated area (102) in order to achieve all the objectives mentioned above and which will emerge from the following detailed description. Thus, the serrated area (102) on the catheter (101, 201, 301) forms a barrier between the catheter (101, 201, 301) and the skin and prevents the infectious microorganisms from entering the body.

BRIEF DESCRIPTION OF THE INVENTION

Figure 1 is a representative view of a general purpose catheter 101 comprising a serrated area according to the present invention. The serrations (104) on the serrated area (102) are positioned on the catheter such that they are perpendicular to the catheter body (103).

In Figure 2, a representative view of the general purpose catheter (101) containing the serrated area (102) of the invention is given. Here the serrations (104) located on the serrated area (102) are positioned on the catheter (101) so that they are inclined towards the lower end of the catheter body (103).

Figure 3 gives a representative view of the general purpose catheter (101) comprising a serrated area according to present invention. The serrations located here (102) are positioned on the catheter (101) such that they are inclined towards the upper end of the catheter body (103).

In Figure 4, a representative view of the central venous catheter (201) comprising the serrated area according to invention is given. The serrations (104) on the serrated area (102) are positioned on the catheter such that they are inclined with respect to the catheter body (203).

In Figure 5, a representative view of the 2A cross section in the body (203) of the central venous catheter (201) according to the invention comprising a serrated area is given.

In Figure 6 a representative view of cross section 2B on the body (203) of the central venous catheter (201) of the invention comprising the serrated area is given.

In Figure 7 a representative view of cross section 2C of the body (203) of the central venous catheter (201) containing the serrated area of the invention is given.

In Figure 8 a representative view of the dialysis catheter (301) comprising the new hole locations and serrated area of the present invention is given. The serrations (104) on the serrated area (102) are positioned on the catheter such that they are inclined with respect to the catheter body (203).

In Figure 9, a representative view of the 3A cross section in the body (303) of the dialysis catheter (301) containing the serrated area of the invention is given.

- 5 In Figure 10, a representative view of the 3D section of the body (303) of the dialysis catheter (301) containing the serrated area of the invention is given.

In Figure 11, a representative view of the front section of the vertical cross section of the area where the holes (308) on the body (303) of the dialysis catheter (301) containing the
10 serrated area according to the invention is given.

Figure 12 is a representative view of the rear section of the vertical cross section where the holes (308) on the body (303) of the dialysis catheter (301) containing the serrated area of the invention is given.

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Figure 13 is a representative view of the cross-section of the exit hole (305) at the lower end (303b) of the body (303) of the dialysis catheter 301 comprising the serrated area of the invention.

20

The reference numbers in the figures and the corresponding sections are listed below;

- 101: General Purpose Catheter
102: Serrated Area
103: Catheter body
25 104: Serration
105: Lower end of catheter body
106: Upper end of catheter body

201: Central venous catheter
30 203: Central venous catheter body
203a: Upper end of central venous catheter body
203b: Lower end of central venous catheter body
205: Central venous catheter 1st path
205a: Central venous catheter 1st path cross section view

- 206: Central venous catheter 2nd path
- 206a: Central venous catheter 2nd path cross section view
- 207: Central venous catheter 3rd path
- 207a: Central venous catheter 3rd path cross section view
- 5 208: Central venous catheter body 1st opening
- 209: Central venous catheter body 2nd opening
- 210: Central venous catheter body 3rd opening
- 2A: Central venous catheter body 1st cross sectional area
- 2B: Central venous catheter body 2nd cross sectional area
- 10 2C: Central venous catheter body 3rd cross sectional area

- 301: Dialysis catheter
- 303: Dialysis catheter body
- 303a: Upper end of dialysis catheter body
- 15 303b: Lower end of dialysis catheter body
- 305: Lower end of dialysis catheter
- 306: Dialysis catheter 1st path
- 306a: Dialysis catheter 1st path cross section view
- 307: Dialysis catheter 2. path
- 20 307a: Dialysis catheter 2nd path cross section view
- 308: Dialysis catheter body 1st opening
- 308a: Dialysis catheter body posterior opening
- 308b: Dialysis catheter body side opening
- 308c: Dialysis catheter body anterior opening
- 25 3A: Dialysis catheter body 1st cross sectional area
- 3B: Dialysis catheter body 2nd cross sectional area

DETAILED DESCRIPTION OF THE INVENTION

- 30 The present invention, in one aspect; refers to catheters (1) having a serrated area (2) on the catheter body (3).

The general-purpose catheters (101) according to the invention comprises a catheter body (103) with a serrated area (102) and the lower end (105) of the catheter body and the upper end (106) of the catheter body.

- 5 In a preferred embodiment of the invention, the catheter having a serrated area to prevent infection is in the form of a central venous catheter (201).

The central venous catheters (201) according to the invention comprise a first path (205), a second path (206) and a third path (207). These three paths mentioned here are located
10 within the body starting from the upper end (203a) of the catheter body. A cross-sectional view (2A) showing the position of all three paths in the body is shown in Figure 5. On the outer surface of the catheter body (203a), i.e., anywhere between the upper end of the catheter body (203a) and the lower end of the catheter body (203b), lies the serrated area (102) with serrations (104) on it. There are also 3 openings on the catheter body (203). As
15 can be seen from the cross section (2B) in the catheter body (203) in figure 3, 2nd and 3rd path is located after the first opening (208). After the second opening (209) on the catheter body, there is the third path as can be seen from the section (2C) in Figure 4. The third opening (210) on the catheter body also shows the catheter tip.

- 20 In a preferred embodiment of the invention, the catheter having a serrated area to prevent infection is in the form of a dialysis catheter (201).

In this context, the current invention is directed to, in a way; dialysis catheters (301) comprising a serrated area (102) on the catheter body (this serrated area may be wavy,
25 Auger-like or grooved, or it may also be described as a dowel) and holes.

The dialysis catheters (301) according to the invention are provided with the first path (306) and the second path (307). These two paths mentioned here are located in the body (303) starting from the upper end (303a) of the catheter body. The cross-section image (3A)
30 showing the position of these two paths within the body (303) is shown in Figure 8. On the outer surface of the catheter body (303a), i.e. anywhere between the upper end of the catheter body (303a) and the lower end of the catheter body (303b), lies the serrated area (102) with serrations (104) on it (Figure 8). There are also 3 or optionally 6 or 9 openings on the catheter body (303). These openings may be 1 or 2 or 3 rows around the catheter

body (303), one side, one anterior and one posterior, wherein all 3 are in one line or slightly above or below with respect to one another, in the form of 1 or 2 or 3 lines. Figure 10 shows the dialysis catheter (301) suitable for the invention, which has 3 openings (308) in one line. One of these openings is on the side (308b) while the others are on the anterior (308c) and on the posterior (308a) position. Through these openings (308a, 308b, 308c) blood enters the catheter. Similarly, when you look at Figure 10, blood is enters into the catheter through the openings indicated by 308a, 308b and 308c, and blood leaves the catheter from the catheter path indicated by 306a. In other words, blood is drawn from the body through the openings (308a, 308b, 308c) and directed to the dialysis device through the catheter path indicated by 307a, in the mean time, the blood exiting the dialysis device is returned to the body through the first path (306) of catheter. The process of introducing blood from the dialysis device is completed by introducing the blood through the catheter lower end 305 (Figure 12).

The dialysis catheter (301) according to the invention has 3 openings, preferably 6 openings, particularly preferably 9 openings. Every 3 of these openings are aligned, such that one in the posterior, one in the side, one in the posterior. The openings in question are in a single row when there are only 3 openings, in 2 rows when there are 6 openings, and in 3 rows when there are 9 openings.

In addition, with the dialysis catheter (301) according to the invention, recirculation has been reduced or prevented. The catheter according to the invention comprises: a) the holes in which the blood enters the catheter is higher, i.e., near the opening of the innominate vein and right subclavian vein into the superior vena cava; c) receives blood from the innominate vein from the anterior opening (308c) with the blood-receiving openings in the anterior position and rear, receiving blood from the right subclavian vein from the posterior opening (308a), blood from the right internal jugular vein from the rear opening (308b); d) delivers the cleared blood from the catheter tip (305) proximally, i.e. within the heart, where the superior vena cava is opened to the heart, thus goal of reduced/prevented recirculation is achieved and the disadvantages of known dialysis catheters are overcome

In the dialysis catheter according to the invention, the holes in which the blood enters the upper side of the catheter and which supply the blood to the dialysis machine are arranged in accordance with human anatomy The catheter is placed though insertion from the vein or

vein of the neck, particularly the internal jugular vein or another large vein, or femoral veins with right or left subclavian veins or both groin veins. The place where the upper multi-hole region of the catheter is to be placed is a region where the above mentioned veins merge in the neck. The subclavian vein from the right side, the innominate vein from the left, the internal jugular vein from the head is poured into this region and they open to the superior vena cava leading to the heart. The location of the catheter should be determined by ultrasound and the catheter should be placed by ultrasound. The holes in which the blood will be taken to the catheter is drawn by especially the holes in the right, from subclavian vein, by the inner holes from the innominate vein. However, all the holes in the vicinity of the internal jugular vein, innominate vein, right subclavian vein and even superior vena can take blood from these an even from the upper part of the cava

The serrated area (102) in the catheters (101, 201, 301) according to the invention comprises serrations (104). These serrations (104) may be towards the lower end of the catheter body (103, 203, 303), towards the upper end, or may be perpendicular to the surface. From another aspect, in the catheter according to present invention (101, 201, 301) the serrations (104) located in the serrated area (102) of the catheter body (103, 203, 303) are positioned to form an angle between 1° and 175° with the catheter body. In the serrated area (102), the angle between the catheter body (103, 203, 303) and the serrations (104) can for example be 5° , 10° , 15° , 20° , 25° , 30° , 35° , 40° , 45° , 50° , 55° , 60° , 65° , 70° , 75° , 80° , 85° , 90° , 100° , 110° , 120° , 130° , 140° , 150° , 160° , 170° .

Serrations (104) forming the serrated area (102) that is on the surface of the catheters (101, 201, 301) in accordance with the invention may have a length ranging from $1\text{ }\mu\text{m}$ to 5 mm. The serrations (104) forming the serrated area (102) on the surface of the catheters according to the invention (101, 201, 301) may all be of a single length of $1\text{ }\mu\text{m}$ and 5 mm or of variable lengths in the range of $1\text{ }\mu\text{m}$. In a preferred application of the invention, serrations (104) can be between $10\text{ }\mu\text{m}$ and 3 mm, especially preferably $50\text{ }\mu\text{m}$ and 2 mm in length. For example, the serrations according to the invention (104) can have a length of $1\text{ }\mu\text{m}$, $5\text{ }\mu\text{m}$, $10\text{ }\mu\text{m}$, $15\text{ }\mu\text{m}$, $20\text{ }\mu\text{m}$, $30\text{ }\mu\text{m}$, $40\text{ }\mu\text{m}$, $50\text{ }\mu\text{m}$, $60\text{ }\mu\text{m}$, $70\text{ }\mu\text{m}$, $80\text{ }\mu\text{m}$, $90\text{ }\mu\text{m}$, 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm.

The serrated area (102) that is on the catheter according to the invention (101, 201, 301) and has serrations (104), may have a length between 1 cm and 10 cm, for example 1 cm, 2 cm, 3

cm, 4 cm, 5 cm, 6 cm, 7 cm, 8 cm, 9 cm, 10 cm long. In a preferred embodiment of the invention, the serrated area (102) on the catheter body (103, 203, 303) may be between 3 cm and 8 cm in length, particularly preferably between 4 cm and 7 cm length.

- 5 The serrations (104) on the catheter (101, 201, 301) according to the invention, forming the serrated area (102), may wrap around the catheter surface in a complete ring, or the serrated area may be in the form of strips with gaps in between. The serrations (104) forming the serrated area (102) may be irregularly distributed over the area (102) or may be arranged at different angles from the catheter body (103, 203, 303), for example a portion of the
- 10 serrations (104) may stand perpendicular to the catheter body while a portion of the serrations (104) are positioned to form an angle between 1° and 175° with the catheter body.

The serrated area (102) with serrations (104) on the catheter according to the invention (101, 201, 301), is located in the subcutaneous portion of the catheter during use of the

15 catheter (101, 201, 301).

As used in the context of the invention, the term "serrated" refers to any shape that protrudes outwardly from the catheter body "103, 203, 303". Accordingly, the term "serrated" as used in the context of the invention may be in the form of conical structures

20 like spikes as shown in Figures 1-13; groove-like protrusions or wavy protrusions or protrusions in the form of triangles or dowels (wall plugs), or combinations thereof.

The serrated area (102) on the catheter (101, 201, 301) according to the invention is intended to form a barrier against bacteria or microorganisms that may penetrate the skin.

25 Barrier is created in two ways:

(i) Granulation tissue occurs during healing of a damaged tissue and acts as a barrier to bacterial passage. A clot is formed between the serrations (104) on the catheter (101, 201, 301) and the catheter-skin-subcutaneous tissue, and granulation tissue is formed herein later. Granulation tissue formation time is shortened by the serrations to prevent or reduce

30 bacterial transmission; and the bacteria transition time is prolonged.

(ii) If the catheter (101, 201, 301) prepared in accordance with the invention is attached or secured to the skin by suture, according to our clinical observations, the catheter (101, 201, 301) may enter or exit the skin from the vein or body cavity, or may be partially outside. The resulting granulation tissue retains the catheter (101, 201, 301), preventing movement

of the catheter (101, 201, 301) in and out, thereby limiting bacterial transport or bacterial passage by the entry and exit of the catheter (101, 201, 301) into and out of the skin.

(iii) the serration (104) around the catheter (101, 201, 301) prepared in accordance with the invention prevents the catheter (101, 201, 301) from dislocation of the catheter after its placement by engaging or attaching to subcutaneous structures due to the shape or inclination of the serrations (104). This feature eliminates the need to suture the catheter or worry of catheter dislocation, especially in cases where daily catheterization is performed.

Catheters according to the invention can be made of metal or polymeric materials. In a preferred embodiment, the catheters according to the invention may be made of metal or polymeric materials which are not affected by or are inert to or do not interact with disinfectants known in the art such as chlorine hexidine, potassium iodide, alcohol and the like.

The catheters (101, 201, 301) according to the invention can be used for any age, height, weight, in other words it can be produced in different types and sizes in accordance with the anatomy of newborn, child, adult or human of different sizes.

In the context of this specification, the expression "comprises" is intended to mean the expression "includes".

Where technically applicable, embodiments of the invention may be combined.

The embodiments are described herein to include certain features / elements. The disclosure also encompasses other embodiments which comprise or consist essentially of said features / elements.

Patents and applications, in particular patent applications TR 2018/20410, TR2018/201413, TR 2018/20419 , and similar technical references are incorporated herein by reference.

The embodiments specifically and explicitly described herein may be the basis for a disclaimer alone or in combination with one or more other embodiments.

CLAIMS

1. A catheter (101) comprising a serrated area (102) having serrations (104) on a catheter body (103)
- 5 2. A catheter according to claim 1 characterized in that the catheter is selected from a group comprising aspiration catheters, urinary catheters, angioplasty balloon catheters, arterioscopes, cannula for neurological or cardiac use, cardiovascular catheters (e.g. angiography, atherectomy, angioplasty, pericardium excretion, septostomy or vulvoplasty catheters), neurological catheters, dialysis catheters,
10 urological catheters, peripheral venous catheters, central venous catheters, peripherally placed central catheters.
3. A catheter according to claim 1-2 characterized in that the catheter is a central venous catheter (201).
- 15 4. A central venous catheter according to claim 3 comprising catheter body (203) and the 1st path (205), the 2nd path (206) and the 3rd path (207) located into the catheter body (203) starting from the upper end of the catheter body (203a) and openings (208, 209, 210) on said catheter body (203) characterized in that the catheter body (203) comprises a serrated area (102) with serrations (102) on it.
- 20 5. A catheter according to claim 1-2 characterized in that the catheter is a dialysis catheter (301)
- 25 6. A dialysis catheter (301) according to claim 5 characterized in that said catheter comprises a 2nd path (307) for delivery of blood from the appropriate vein to the dialysis device, a 1st path (306) for delivery of blood exiting the dialysis device to the body, a catheter tip (305) for delivering blood to the body from path 1, a catheter body wherein these paths are located (303), openings (308) on the catheter body for withdrawing blood from the body, and a serrated area (102) on the catheter body with serrations (104) thereon.
7. A dialysis catheter (301) according to claims 5-6, characterized in that there are 3 or preferably 6 or particularly preferably 9 openings (308) on the catheter body.
- 30 8. A dialysis catheter (301) according to claims 5-7 characterized in that it comprises openings in 1 or 2 or 3 rows wherein one is on the side, another is anterior and another one is posterior such that in one row there are 3 openings.

9. A catheter (101, 201, 301) according to claims 1-8 characterized in that the serrations (104) located on the serrated area (102) are positioned such that they are perpendicular to the catheter body (103, 203, 303)

10. A catheter (101, 201, 301) according to claims 1-9 characterized in that the serrations (104) on the serrated area (102) are positioned so that they are inclined towards the bottom of the catheter body (103, 203, 303).

11. A catheter (101, 201, 301) according to claims 1-10 characterized in that the serrations (104) located on the serrated area (102) are positioned so that they are inclined towards the top of the catheter body (103, 203, 303).

12. A catheter (101, 201, 301) according to claims 1-11 characterized in that the serrations (104) on the serrated area are positioned to form an angle between 1° and 175° with the catheter body.

13. A catheter (101, 201, 301) according to claims 1-12 characterized in that the serrations (104) forming the serrated area (102) have a length ranging from $1\text{ }\mu\text{m}$ to 5 mm.

14. A catheter (101, 201, 301) according to claims 1-13 characterized in that the serrated area (102) located on the catheter body (103, 203, 303) has a length between 1 cm and 10 cm

15. A catheter (101, 201, 301) according to claims 1-14 characterized in that the catheter is made of metal or polymeric material.

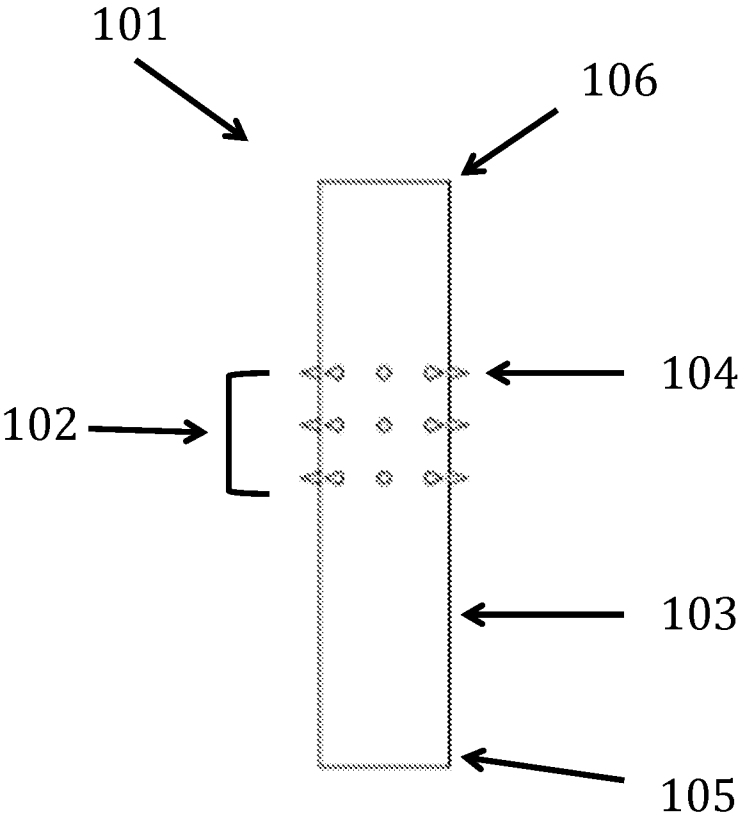


Figure 1

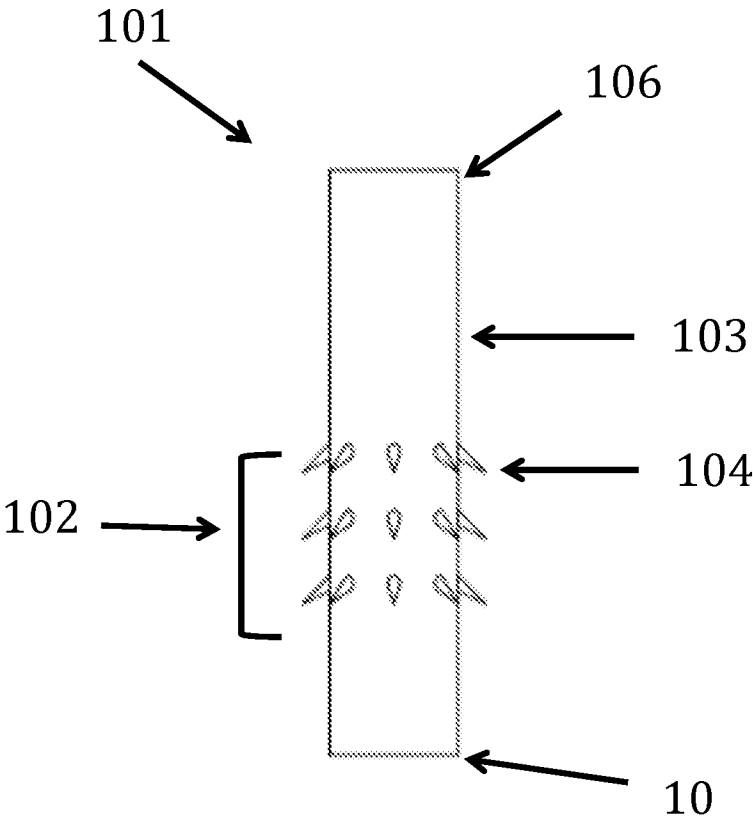


Figure 2

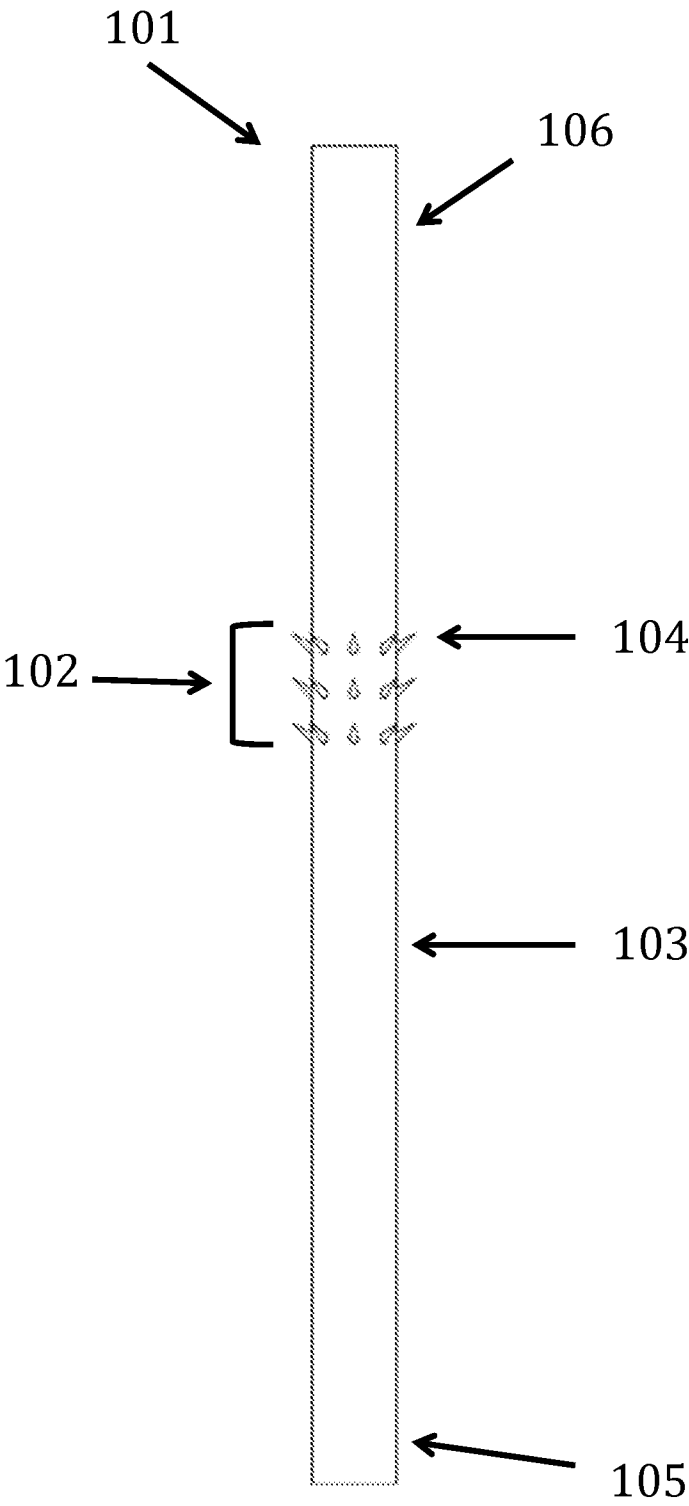


Figure 3

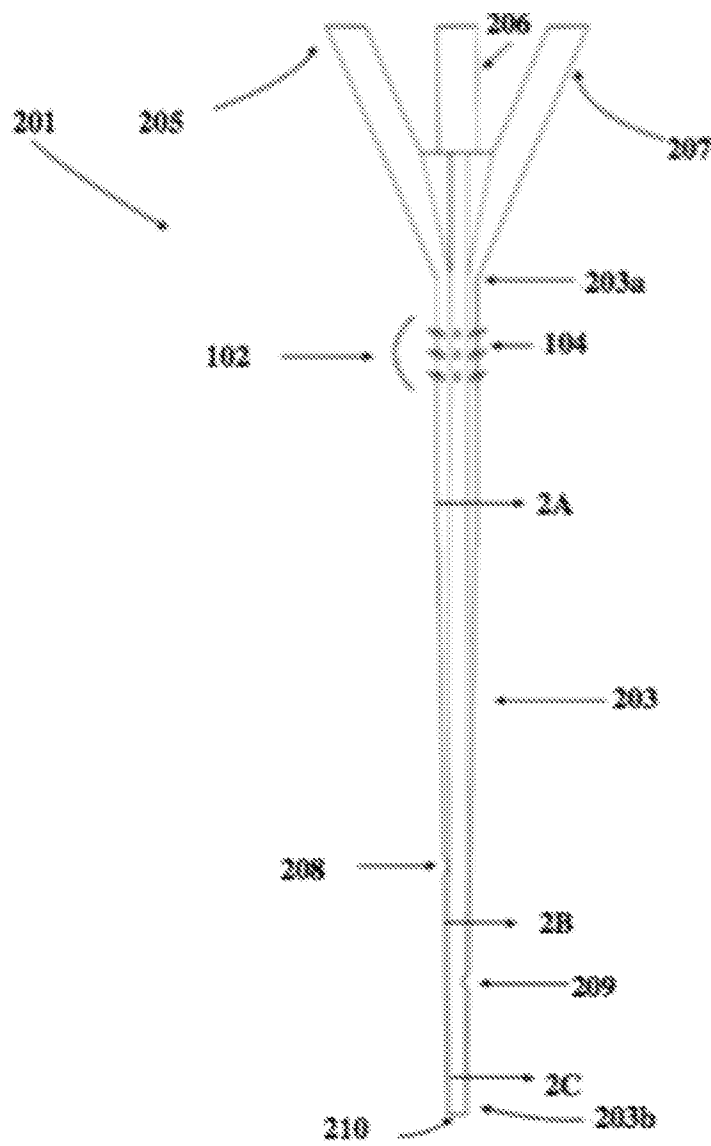


Figure 4

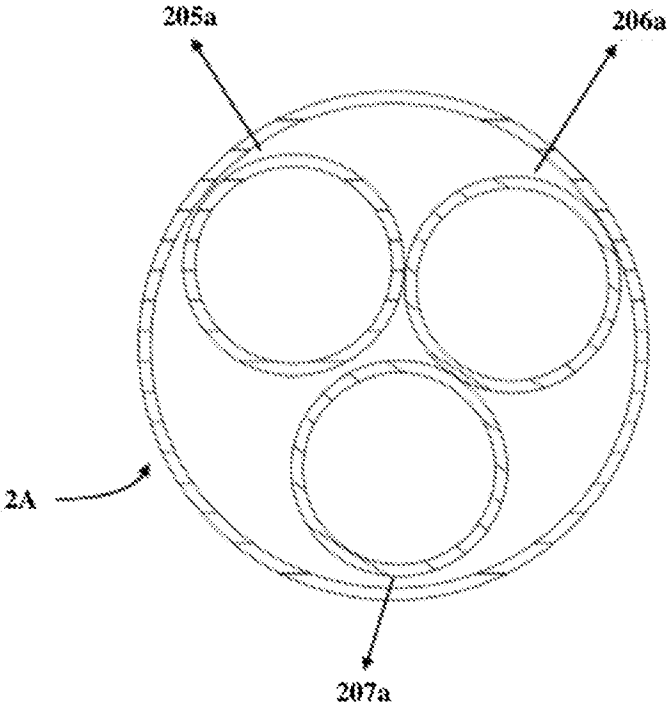


Figure 5

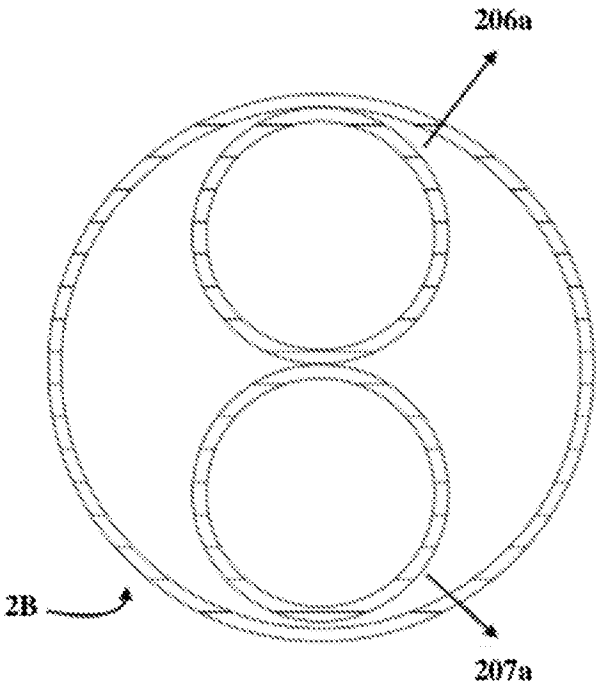


Figure 6

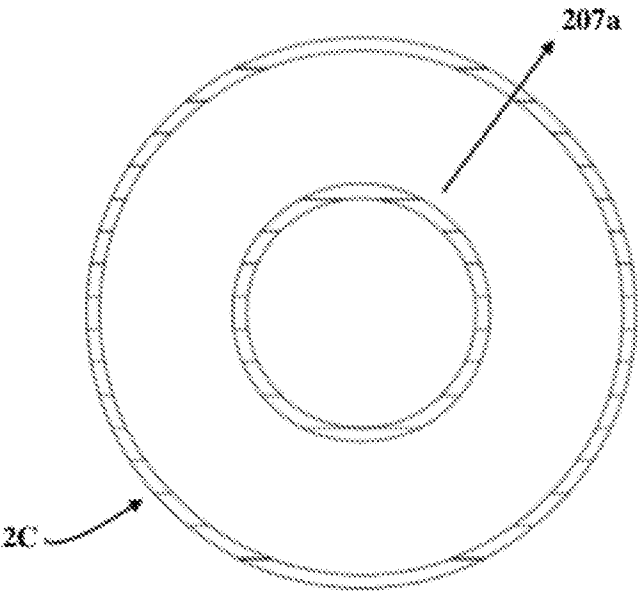


Figure 7

7/11

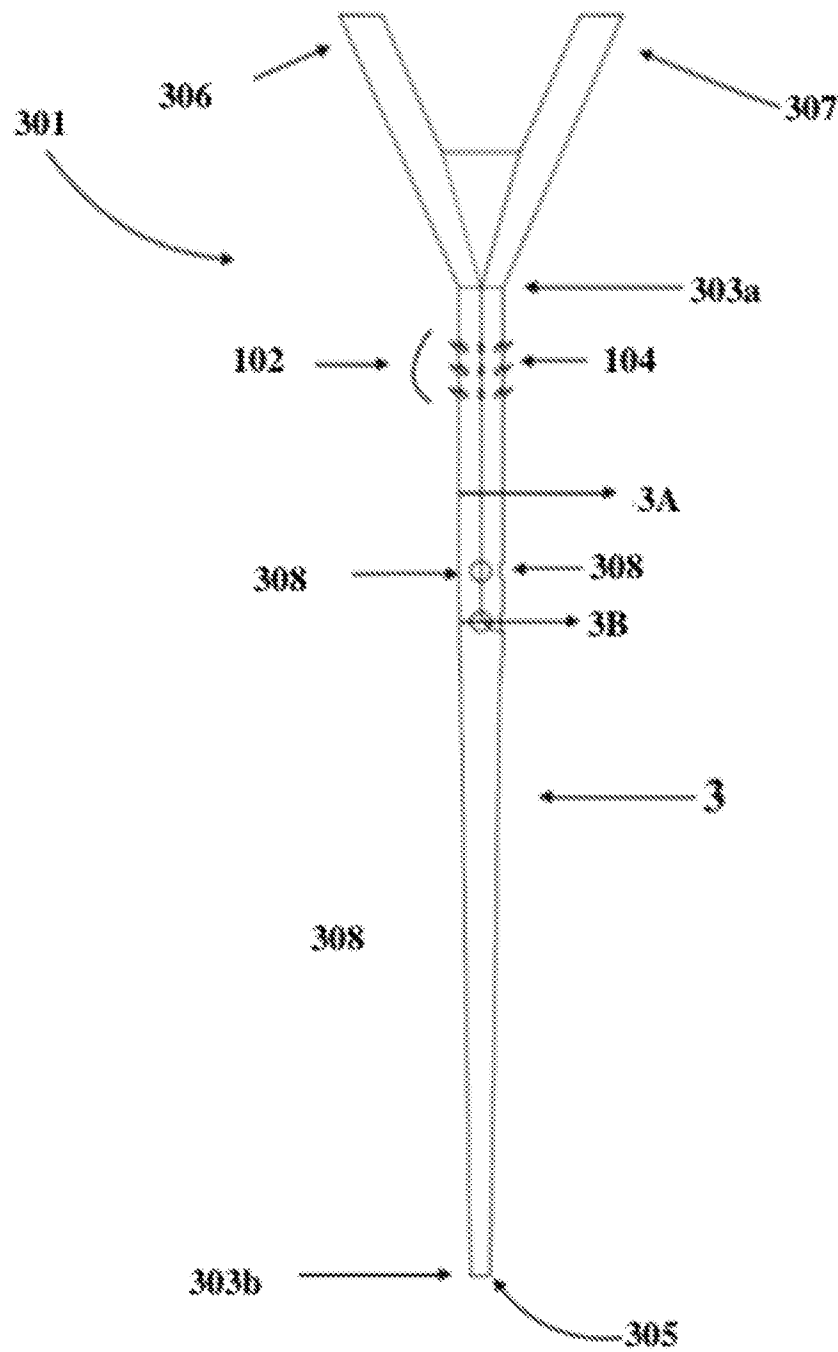


Figure 8

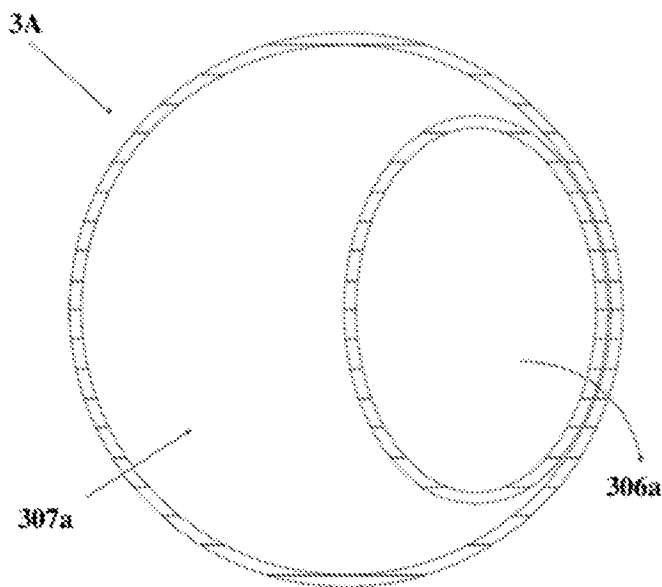


Figure 9

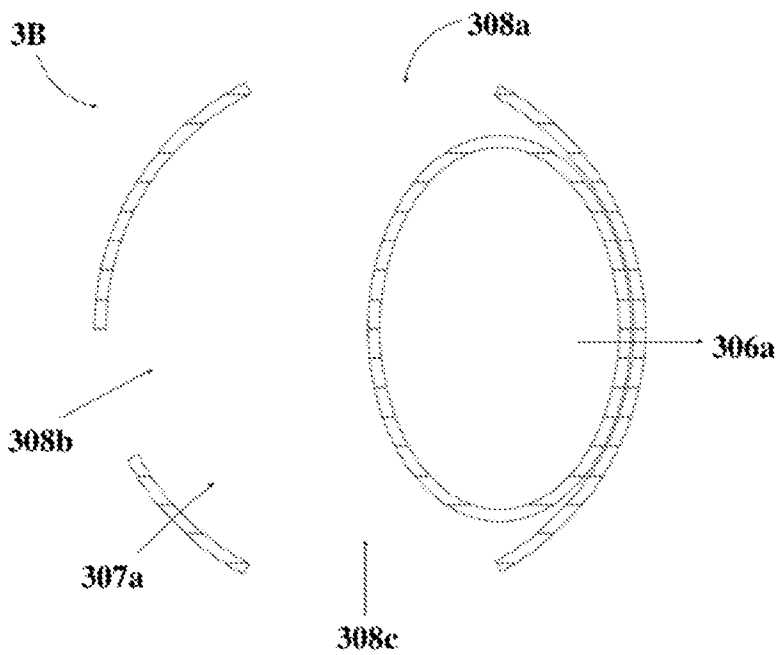


Figure 10

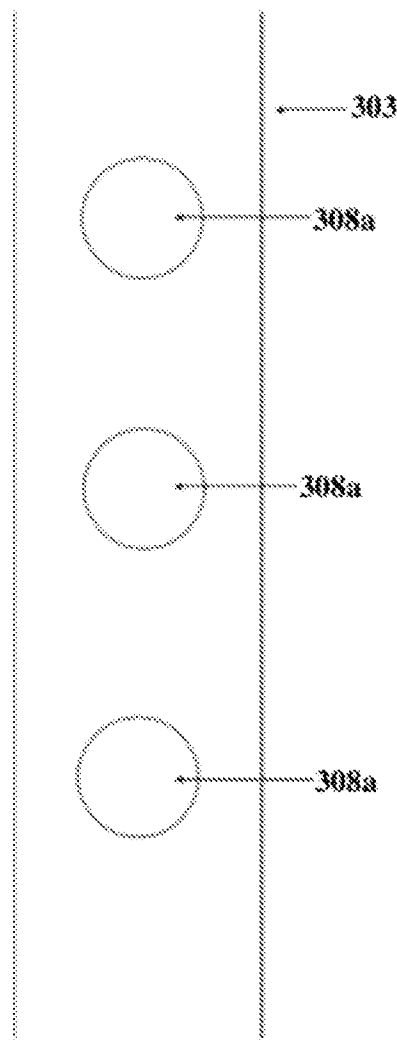


Figure 11

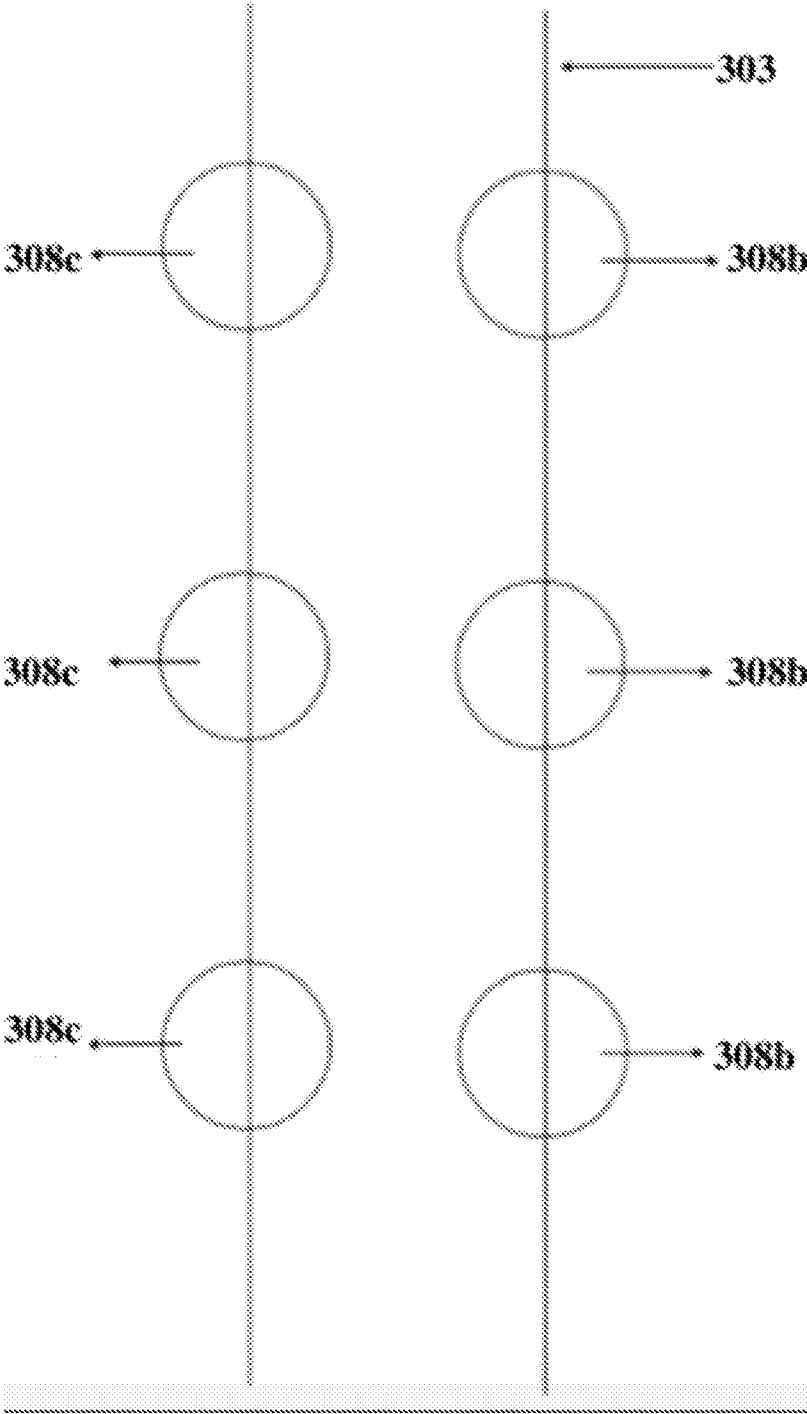


Figure 12

11/11

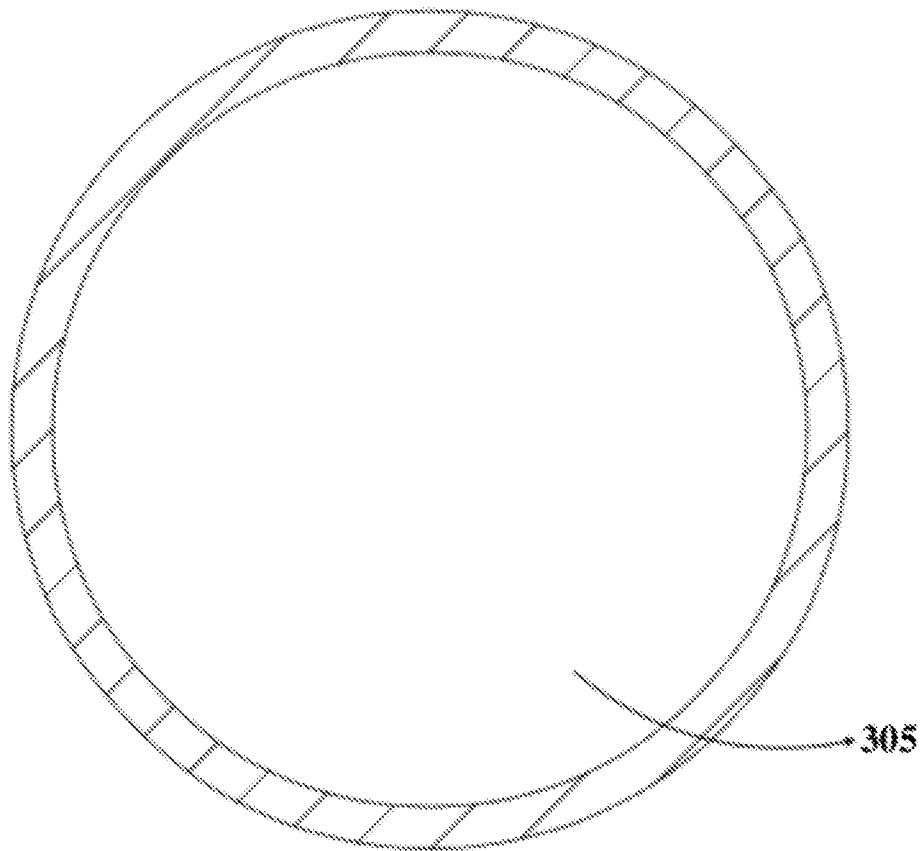


Figure 13